AUG 2 7 2001

Section 2 - 510(k) Summary and Certification

[As required by 21 CFR 807.92(c)]

1. *Submitter's Name / Contact Person*

Jack Slovick
Director, Quality and Regulatory Affairs

Tel: (763) 315-0013
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NeuroVasx, Inc.
7351 Kirkwood Lane, Suite 112
Maple Grove, MN 55369

2. *General Information*

Trade Name: NeuroEdge™ Infusion Catheter

Classification Name: Continuous Flush Catheter

Classification: This device is classified by the Circulatory Systems Device Panel into Class II, (21 CFR 870.1210)

3. *Device Description*

The NeuroEdge™ Infusion Catheter is a single use, 1.4 Fr device designed to fit within a standard microcatheter for advancement to, and navigation of a lesion site. A nitinol mandrel within the NeuroEdge™ Infusion Catheter lumen facilitates axial movement and stability during navigation. The catheter is designed to infuse liquid agents (such as contrast media and liquid embolic glues) through the end hole at select sites in the neurovasculature for the diagnosis, visualization, and treatment of arterio-venous malformations/fistulas (AVM/AVF's), lesions, or embolisms. The catheter is also designed to penetrate an embolism if it is determined to be a soft thrombus and navigate through the thrombus to assess the circulation distal to the thrombus.

The NeuroEdge™ Infusion Catheter is contained in a plastic hoop assembly and sealed in a Tyvek / polyester pouch. The sealed pouch assembly is labeled and placed in a shelf carton along with the instructions for use, and then sterilized via gamma radiation sterilization process. (See Attachment B for device drawings.)

4. *Intended Use*

The NeuroEdge™ Infusion Catheter is intended for the infusion of various diagnostic, embolic and therapeutic agents into the neurovasculature.

5. Substantial Equivalence Comparison

The NeuroEdge Infusion Catheter is substantially equivalent to the following devices with respect to intended use, design, materials and construction:

- NeuroVasx Sub-MicroInfusion Catheter, NeuroVasx Inc. (K984258)
- Prowler™-10 Infusion Catheter, Cordis Endovascular Systems Inc. (K003925)
- LTD Torque Device, B. Braun Medical, (K964352)

6. Summary of Studies

Performance testing was completed to verify the design specifications necessary for the open-ended modification and to support the compatibility of the catheter to deliver embolic / therapeutic agents. Test results support the safety and performance of the NeuroEdge™ Infusion Catheter for its intended use.

7. Conclusion (statement of equivalence)

The data and information provided in this submission supports a substantial equivalence determination, and, therefore, 510(k) premarket notification clearance of the NeuroEdge™ Infusion Catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Jack Slovick
Director, Regulatory Affairs/Quality Assurance
NeuroVasx, Inc.
7351 Kirkwood Lane, Suite 112
Maple Grove, Minnesota 55369

Re: K011646
Trade/Device Name: NeuroEdge™ Infusion Catheter
Regulation Number: 870.1210
Regulatory Class: II
Product Code: KRA
Dated: May 25, 2001
Received: May 29, 2001

Dear Mr. Slovick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K011646

Indications for Use Statement

The NeuroEdge™ Infusion Catheter is intended for the infusion of various diagnostic, embolic and therapeutic agents into the neurovasculature.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011646

MAY 25, 2001